



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2012-0775 and EPA-HQ-OPP-2013-0008; FRL-9905-87]**

### **Saflufenacil; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of saflufenacil in or on multiple commodities which are identified and discussed later in this document. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the **Federal Register***]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the **Federal Register***], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The dockets in this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0775 and EPA-HQ-OPP-2013-0008, are available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday,

excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify the docket ID number EPA-HQ-OPP-2012-0775 and/or EPA-HQ-OPP-2013-0008 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0775 and/or EPA-HQ-OPP-2013-0008, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of November 7, 2012 (77 FR 66781) (FRL-9367-5) (EPA-HQ-OPP-2012-0775), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8065) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide, saflufenacil, including its metabolites and degradates, in or on sugarcane, cane at 0.03 parts per million (ppm); sugarcane, molasses at 0.075 ppm; and sugarcane, refined sugar at 0.045 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of February 27, 2013 (78 FR 13295) (FRL-9380-2) (EPA-HQ-OPP-2013-0008), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8139) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide, saflufenacil, including its metabolites and

degradates, in or on crayfish at 0.01 ppm. In the **Federal Register** of December 30, 2013 (78 FR 79359) (FRL-9903-69) (EPA-HQ-OPP-2013-0008) EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing a revision to the original pesticide petition (PP 2F8139) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The revised petition requested that 40 CFR 180.649 be amended by establishing tolerances for residues of the herbicide, saflufenacil, including its metabolites and degradates, in or on fish-freshwater finfish and fish-shellfish crustacean at 0.01 ppm instead of “crayfish at 0.01 ppm” based on the Agency’s evaluation of the data supporting the original petition. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

In the **Federal Register** of June 5, 2013 (78 FR 33785) (FRL-9386-2) (EPA-HQ-OPP-2013-0008), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2F8129) by BASF Corporation, 26 Davis Dr., P.O. Box 13528, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR 180.649 be amended by amending tolerances for residues of the herbicide, saflufenacil, including its metabolites and degradates, in or on rice, straw at 0.30 ppm and amend the current commodity definition “Grain, cereal, forage, fodder and straw group 16” to “Grain, cereal, forage, fodder and straw group 16 (except rice straw).” That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket,

<http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petitions, EPA has determined that the tolerance level of 0.03 ppm requested for sugarcane, cane is increased to 0.05 ppm; and the tolerance level of 0.075 ppm requested for sugarcane, molasses is increased to 0.08 ppm. Additionally, tolerances requested for sugarcane, refined sugar and rice, straw are not being established at this time. The reasons for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the

hazards of and to make a determination on aggregate exposure for saflufenacil including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with saflufenacil follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Saflufenacil has low acute toxicity via all routes of exposure. Subchronic and chronic toxicity studies in rats, mice, and dogs identified the hematopoietic system as the primary target of saflufenacil. Consistent with its proposed mode of toxicity involving protoporphyrinogen IX oxidase (PPO) inhibition and subsequent disruption of heme biosynthesis, decreased hematological parameters were seen at about the same dose level [lowest-observed adverse-effect levels (LOAELs) of 13-39 milligram/kilogram/day (mg/kg/day)] across species, except in the case of the dog, where the effects were seen at a slightly higher dose (LOAELs of 50-100 mg/kg/day). These effects occurred around the same dose level from short- through long-term exposures without increasing in severity. In line with findings that male rats achieve a greater systemic exposure than females, males were the most sensitive sex in mice and rats. Effects were also seen in the liver (increased weight, centrilobular fatty change, lymphoid infiltrate) in mice, the spleen (increased spleen weight and extramedullary hematopoiesis) in rats, and in both of these organs (increased iron storage in the liver and extramedullary hematopoiesis in the

spleen) in dogs. These effects also occurred around the same dose level from short-through long-term exposures without increasing in severity.

Increased fetal susceptibility was observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects (decreased fetal body weights and increased skeletal variations in rats and increased liver porphyrins in rabbits) occurred at doses that were not maternally toxic, indicating increased quantitative susceptibility. In the 2-generation reproductive toxicity study in rats, the reported offspring effects were more severe than the maternal effects at the same dose level, indicating evidence for increased qualitative susceptibility. An increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters occurred at the same dose level as maternal decrements in food intake, body weight, body-weight gain, and changes in hematological parameters and organ weights indicative of anemia.

There is no evidence of neurotoxicity or immunotoxicity in the saflufenacil database.

Saflufenacil was weakly clastogenic in the *in vitro* chromosomal aberration assay in V79 cells in the presence of S9 activation; however, the response was not evident in the absence of S9 activation. It was neither mutagenic in bacterial cells nor clastogenic in rodents *in vivo*. Carcinogenicity studies in rats and mice showed no evidence of increased incidence of tumors at the tested doses. Saflufenacil is classified as “not likely carcinogenic to humans.”



Specific information on the studies received and the nature of the adverse effects caused by saflufenacil as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Saflufenacil. Human-Health Risk Assessment in Support of Tolerances for Residues in/on Fish, Crayfish, and Imported Sugarcane” at p. 26 in docket ID numbers EPA-HQ-OPP-2012-0775 and EPA-HQ-OPP-2013-0008.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for saflufenacil used for human risk assessment is shown in Table 1 of this unit.

**TABLE 1.--SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SAFLUFENACIL FOR USE IN HUMAN HEALTH RISK ASSESSMENT**

<b>Exposure/Scenario</b>	<b>Point of Departure and Uncertainty/Safety Factors</b>	<b>RfD, PAD, LOC for Risk Assessment</b>	<b>Study and Toxicological Effects</b>
Acute dietary (General population including infants and children)	NOAEL = 500 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Acute RfD = 5.0 mg/kg/day  aPAD = 5.0 mg/kg/day	Acute Neurotoxicity Study (rat)  LOAEL = 2,000 mg/kg/day based on decreased motor activity representing mild and transient systemic toxicity in male rats.
Chronic dietary (All populations)	NOAEL= 4.6 mg/kg/day UF <sub>A</sub> = 10X UF <sub>H</sub> = 10X FQPA SF = 1X	Chronic RfD = 0.046 mg/kg/day  cPAD = 0.046 mg/kg/day	Chronic/Carcinogenicity (mouse)  LOAEL = 13.8 mg/kg/day based on decreased red blood cells, hemoglobin, hematocrit, and porphyria observed in the satellite group.
Cancer (Oral, dermal, inhalation)	Not likely carcinogenic to humans based on the lack of tumors in the mouse and rat carcinogenicity studies and lack of mutagenicity.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor.  $UF_A$  = extrapolation from animal to human (interspecies).  $UF_H$  = potential variation in sensitivity among members of the human population (intraspecies).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to saflufenacil, EPA considered exposure under the petitioned-for tolerances as well as all existing saflufenacil tolerances in 40 CFR 180.649. EPA assessed dietary exposures from saflufenacil in food as follows:

i. *Acute and chronic exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for saflufenacil.

In estimating both acute and chronic dietary exposure, EPA used the Dietary Exposure Evaluation Model--Food Consumption Intake Database (DEEM) which incorporates food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA; 2003-2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), DEEM 7.81 default processing factors, and tolerance-level or higher (i.e., tolerance levels adjusted to take into account metabolite levels) residues for all foods.

ii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that saflufenacil does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iii. *Anticipated residue and PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for saflufenacil. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for saflufenacil in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of saflufenacil. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model and Tier II Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of saflufenacil for acute exposures are estimated to be 133 parts per billion (ppb) for surface water and 69.2 ppb for ground water. Chronic exposures for non-cancer assessments are estimated to be 120 ppb for surface water and 51.5 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 133 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 120 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Saflufenacil is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.” EPA has not found saflufenacil to share a common mechanism of toxicity with any other substances, and saflufenacil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that saflufenacil does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is

commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Increased fetal susceptibility was observed in the developmental toxicity studies in the rat and rabbit and in the 2-generation reproduction study in the rat. Developmental effects (decreased fetal body weights and increased skeletal variations in rats and increased liver porphyrins in rabbits) occurred at doses that were not maternally toxic in the developmental studies, indicating increased quantitative susceptibility. In the 2-generation reproductive toxicity study in rats, the reported offspring effects were more severe than the maternal effects at the same dose level, indicating evidence for increased qualitative susceptibility. An increased number of stillborn pups, decreased viability and lactation indices, decreased pre-weaning body weight and/or body-weight gain, and changes in hematological parameters occurred at the same dose level as maternal decrements in food intake, body weight, body-weight gain, and changes in hematological parameters and organ weights indicative of anemia.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for saflufenacil is complete.
- ii. There is no indication that saflufenacil is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. The concern for increased susceptibility following prenatal or postnatal exposure is low because clear NOAELs/LOAELs were established for the developmental effects seen in rats and rabbits as well as for the offspring effects seen in the 2-generation reproductive toxicity study. Further, the dose-response relationship for the effects of concern is also well characterized and being used for assessing risks. None of the effects in the developmental or reproduction studies were attributable to a single exposure and, therefore, are not of concern for acute risk assessment. The chronic point of departure used for risk assessment is protective of any developmental and offspring effects observed in these studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to saflufenacil in drinking water. These assessments will not underestimate the exposure and risks posed by saflufenacil.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to saflufenacil will occupy

<1% of the aPAD for infants less than 1-year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to saflufenacil from food and water will utilize 18% of the cPAD for infants <1-year old, the population group receiving the greatest exposure. There are no residential uses for saflufenacil.

3. *Short and intermediate-term risk.* Short and intermediate-term aggregate exposure takes into account short and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Because there is no short or intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term risk for saflufenacil.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, saflufenacil is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to saflufenacil residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*



Adequate enforcement methods “D0603/02” and “L0073/01” (liquid chromatography/mass spectroscopy/mass spectroscopy (LC-MS/MS)) are available to enforce the tolerance expression. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for saflufenacil.

#### *C. Revisions to Petitioned-For Tolerances*

EPA has increased the tolerance level requested by BASF Corporation in petition 2E8065 for sugarcane, cane from 0.03 ppm to 0.05 ppm based on the residue data for sugarcane and use of the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures. Also, based on the residue data for sugarcane

and to account for concentrations of residues during processing, a tolerance of 0.08 ppm is required for residues in or on sugarcane, molasses. Residues did not concentrate in refined sugar, so the tolerance proposed for this commodity will not be established at this time. In addition, the proposed tolerances for rice straw in PP 2F8129 will not be established since rice straw is not a significant livestock item. Therefore, the associated request for a change in the commodity definition is not necessary.

## V. Conclusion

Therefore, tolerances are established for residues of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites and degradates in or on sugarcane, cane at 0.05 ppm and sugarcane, molasses at 0.08 ppm. Also, tolerances are established for residues of the parent, saflufenacil, in fish-freshwater finfish and fish-shellfish, crustacean at 0.01 ppm. Compliance with the sugarcane, cane and sugarcane, molasses tolerances is to be determined by measuring the sum of saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)- 1(2*H*)-pyrimidinyl]-4-fluoro-*N* -[[methyl(1-methylethyl)amino]sulfonyl]benzamide, and its metabolites *N*-[2-chloro-5-(2,6-dioxo-4-(trifluoromethyl)-3,6-dihydro-1(2*H*)-pyrimidinyl)-4-fluorobenzoyl]-*N*-isopropylsulfamide and *N*-[4-chloro-2-fluoro-5-(((isopropylamino)sulfonyl)amino)carbonyl)phenyl]urea calculated as the stoichiometric equivalent of saflufenacil; compliance with the fish-freshwater finfish and fish-shellfish, crustacean tolerances are to be determined by measuring only saflufenacil, 2-chloro-5-[3,6-dihydro-3-methyl-2,6-dioxo-4-(trifluoromethyl)-1(2*H*)-pyrimidinyl]-4-fluoro-*N*-[[methyl(1-methylethyl)amino]sulfonyl]benzamide.

## **VI. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the

relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 11, 2014.

Lois Rossi,

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.649:

a. Add alphabetically the following commodities and footnote 2 to the table in paragraph (a)(1).

b. Add alphabetically the following commodities to the table in paragraph (a)(2).

The amendments read as follows:

**§ 180.649 Saflufenacil; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * *	* *
Sugarcane, cane <sup>2</sup>	0.05
Sugarcane, molasses <sup>2</sup>	0.08
* * *	* *

\* \* \* \*

<sup>2</sup> No U.S. registration as of [*insert date of publication in the Federal Register*].

(2) \* \* \*

Commodity	Parts per million
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* * *	* *
Fish-freshwater finfish	0.01
Fish-shellfish, crustacean	0.01
* * *	* *

\* \* \* \*

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